



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

ACTION ITEMS – April 2004 BOARD MEETING

The board packet materials for this meeting are available on the board's Web site.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

The board:

- Approved a pilot program to have the pharmacy students at UCSF and UCSD develop consumer fact sheets on various health care topics.
- Agreed to participate on a project with UCSF School of Pharmacy to produce educational materials on Atrial Fibrillation (Afib). Funding for the materials would come from a drug manufacturer and the board's role would be to place the materials on the board's Web site and help publicize the materials. There will be no direct costs to the board.
- Added three tasks to its strategic plan for 2004/05 to reflect several activities initiated or planned for next year for the Communication and Public Education Committee. The tasks include: evaluation of the need for labeling a prescription in a language other than English, creation of consumer fact sheet series in conjunction with the schools of pharmacy, and creation of public education activities on the changes to the controlled substance laws.
- Agreed to work with UCSF to develop a *Health Notes* on smoking cessation, and seek funding for this issue from manufacturers of smoking cessation products.
- Reported that the March 2004 edition of *The Script* has been distributed to all California pharmacies and the California Pharmacists Association will be distributing this newsletter to all California pharmacists. It is also available on the board's Web site.
- Reported that staff is working on publishing a new *Health Notes on Pain Management*. This new issue will contain new pain management therapies and the new prescribing and dispensing requirements for controlled drugs enacted by SB 151 (Burton, Chapter 406), which will take place in 2004 through 2005 in sequential stages. The goal is to have this publication available for distribution in July 2004.
- Reported that a short fact sheet on the federal Medicare Discount Drug Program has been developed and is on the board's Web site. The fact sheet advises the public about how they can avoid becoming a victim of a consumer scam involving the drug discount card. The board's information also refers the public to the federal government's Medicare Web site and to an 800 number for more information about the cards.

ENFORCEMENT COMMITTEE

The board:

- Revised its public disclosure policy and agreed to keep its current record retention period of 5 years for substantiated complaints and investigations. The board's Web site look-up for disciplinary actions is available and includes disciplinary cases from January 1, 1998. The board directed that the Enforcement Committee review the request from licensees to include "disclaimer" language with the public release of

citation and fine information that states when a licensee pays a fine that payment of the fine does not constitute an admission to the violation charged.

- Added a new strategic objective for 2004/05 that directs the Enforcement Committee to review 25 emerging enforcement issues by June 30, 2005.
- Clarified that pharmacies can keep drug purchase records from wholesalers electronically rather than on paper so long as those records are retained on site and immediately available for inspection for a period of three years, and must at all times be produced in both hard copy and electronic form by an on-duty pharmacist. The board will publish this information on its Web site and in its next newsletter.
- Clarified that there is at present no statutory or regulatory requirement that a licensee check 100% of all prescriptions dispensed by an automated delivery system. However, the licensee is responsible for any error that does occur. The board will publish this information on its Web site and in its next newsletter.
- Discussed the importation of prescription drugs from Canada and the task of balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The board reported that the federal Food and Drug Administration on behalf of the U.S. Department of Health and Human Services' (HHS) Task Force on Importation, held a public meeting on April 14th so that individuals, organizations and other stakeholders could present information to the Task Force for consideration in the study on importation mandated by the Medicare Prescription Drug Improvement and Modernization Act of 2003. The Task Force is interested in information related to whether and under what circumstances drug importation could be conducted safely, and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients. Comments may be submitted until June 1, 2004. The board will obtain minutes from the April 14th meeting.
- Reported on the implementation of SB 151(Burton, Chapter 406). This bill repeals the triplicate prescription requirement for schedule II controlled substance prescriptions and replaces it with a tamper-resistant prescription form that may be obtained from approved printers. Two security printers have been approved.

LICENSING COMMITTEE

The board:

- Approved the reconfiguration of the Competency Committee to a two-tier structure that will be a group of item writers to develop questions for the California Pharmacist Jurisprudence Examination (CPJE) and a core committee that will select and refine the questions for the examination, select a cut-score and oversee the examination administration.
- Voted to sponsor legislation to extend the provision that requires an applicant who has failed the board's pharmacist licensure examination four or more times to take an additional 16 units of pharmacy education. This provision would be extended to the board's next sunset review in 2006.
- Agreed to amend CCR, title 16, sec. 1719 to recognize those schools of pharmacy that have been granted "candidate" status by the Accreditation Council for Pharmacy Education (ACPE) for purposes of application for an intern registration and being admitted the pharmacist licensure examination.
- Accepted the recommended changes from the Medical Board of California to the statewide protocol for pharmacists to dispense emergency contraception and approved the protocol in accordance with Senate Bill 490 (Chapter 651, Statutes of 2003). The board adopted the protocol as an emergency regulation if approved by the Medical Board of California.

- Granted a waiver pursuant to CCR, title 16, sec. 1706.5 to Cedars-Sinai Medical Center to conduct a study with UCSF, School of Pharmacy to determine the impact of using technicians checking technicians to fill unit dose cassettes on patient care. The study is approved for two years, from April 21, 2004 – April 21, 2006.
- Agreed to sponsor a legislative change for inclusion in the 2004 omnibus bill that would give clear statutory authority to request information needed to evaluate the qualifications of any applicant.
- Reported on the implementation of NAPLEX and the California Pharmacist Jurisprudence Examination (CPJE). The contracts have been approved and the administration of these examinations via computer terminals has begun. Both examinations are available six days a week at designated testing locations across the United States. There are 125 sites for the CPJE. The board's goal is to, once all procedures are in place, release the examination results within 15 days following the NAPLEX and approximately 30 days following the CPJE. Information on the new examination process and the application forms are available on the board's Web site.
- Provided the March 3rd meeting summary for the Workgroup on Compounding.

LEGISLATION AND REGULATION COMMITTEE

The board:

- Received approval from the Administration to submit the rulemaking file on sterile compounding to the Office of Administrative Law (OAL). The OAL disapproved the rulemaking file because the California Building Standards Commission had not approved the regulation amendments. The commission must review and approve all building standards proposed and adopted by state agencies. The board has 120 days to resubmit the rulemaking file to OAL.
- Adopted final language to amend the following regulations. The board will compile the rulemaking file for submission to the Administration and the Office of Administrative Law for approval. The regulations are:
 1. CCR, title 16, sec. 1709.1 – Pharmacist-in-Charge at Two Locations
 2. CCR, title 16, sec. 1710 - Hospital Central Fill
 3. CCR, title 16, sec. 1711 - Notification of a Prescription Error
 4. CCR, title 16, sec. 1717.1 - Common Electronic Files
 5. CCR, title 16, sec. 1717.4 – Authentication of Electronic Prescriptions
 6. CCR, title 16, sec. 1720 – Pharmacist License Process
 7. CCR, title 16, sec. 1721 – Pharmacist Exam
 8. CCR, title 16, sec. 1723.1 – Confidentiality of Exam Questions
 9. CCR, title 16, sec. 1724 – Passing Score
 10. CCR, title 16, sec. 1749 and 1793 et seq. – Pharmacy Technicians
 11. CCR, title 16, sec. 1793.3 – Non-Licensed Person Ratio (Clerk-typist)
- Took positions on the following legislative bills:

AB 320	Correa	Prohibits "regulatory gag clauses" in malpractice settlements.	Support
AB 1826	Bogh	Adds the theft of professional license numbers to identity theft statutes.	Support
AB 1960	Pavley	Requires the board to license PBMs. Specifies contract terms and disclosures by PBMs.	Oppose Unless Amended

AB 2184	Plescia	Allows pharmacies to operate automated dispensing devices in skilled nursing and intermediate care facilities.	Support
AB 2660	Leno	Requires pharmacists working under protocol to obtain DEA registration numbers.	Support
AB 2682	Negrete McLeod	Requires all out of state distributors to be licensed by the board.	Support if Amended
SB 1159	Vasconcellos	Repeals the prescription requirement for needles and syringes.	Support
SB 1307	Figueroa	Requires drug pedigrees, increases licensing requirements for wholesalers, increased penalties for certain wholesaling violations, and restricts wholesale transactions by pharmacies.	Board Sponsored
SB 1427	Ackerman	Imposes a felony for drug counterfeiting.	Support
SB 1563	Escutia	Requires wholesalers contracting with the state to extend 340B drug discounts to "safety net" providers.	Oppose Unless Amended
SB 1735	Figueroa	Exempts DCA boards and bureaus from hiring freeze and restores vacant positions recently eliminated.	Support
SB 1913	Business and Professions Committee	Annual omnibus bill with technical and non-controversial changes to pharmacy law.	Board Sponsored

- Voted to take no position on AB 1957 (Frommer) and SB 1149 on drug importation.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

The board:

- Elected Stan Goldenberg, R.Ph. as President, Bill Powers, public member as Vice-President, and David Fong, Pharm.D as Treasurer
- Agreed to revise the board member procedures manual to clarify that the participation of board members during committee meetings is limited by the number of board members in attendance and to reflect the board's current structure and operations.
- Agreed to hold public meetings of the two-board member Organizational Development Committee when there is likely to be high interest in matters to be discussed.
- Approved the board's strategic plan for 2004/05, incorporating all changes made to the committees' strategic objectives approved during this board meeting.
- Reported that California is an active member of the National Association of Boards of Pharmacy (NABP).
- Approved the meeting dates for 2005 – January 19 and 20, April 27 and 28, July 20 and 21 and October 25 and 26.

- Reported on its 2003/04 and 2004/05 budget. The board's proposed budget for 2004/05 contains no new spending proposals and as such, the board will continue to operate in the same manner, and with the same resources as this year. (This includes a 12 percent, or \$411,000, cut in Personnel Services, which is linked to the loss of six positions, cuts to board member compensation, overtime, and operations.) The Governor's Office and the Department of Finance have stated in recent budget instructions that there will be "no discretionary funds available from any source for new initiatives or program expansion." As such, any new legislative mandates or program modifications must be funded within existing resources. It was also reported that the AG's hourly rates for legal services increased April 1st. These additional fees will have to be absorbed this year; however, the department may be developing a budget change proposal to augment all agencies' budgets to cover the increase for next year, which may or may not be approved.
- Announced the resignation of Inspector Rosie Yongvanich to become a full-time parent. The board is seeking a hiring freeze exemption to fill the vacancy.
- Provided the 360-day post audit status report on the findings of the operational audit of the board to Department of Consumer Affairs, Internal Audits Office.
- Approved the minutes of the January 21 and 22, 2004 Board Meeting.